Docket No.: 28903.0003

PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: James A. [redacted]ELL, et al.

GROUP ART UNIT: Unassigned

SERIAL NUMBER: 10/549,804

EXAMINER: Unassigned

FILED: September 19, 2005

FOR: PLASMINOGEN ACTIVATOR INHIBITOR-1 (PAI-1) HAPLOTYPES USEFUL AS INDICATORS OF PATIENT OUTCOME

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant(s) wish to disclose the following information.

REFERENCES

■ The Applicant(s) wish to make of record the references listed on the attached PTO/ SB/08. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.

☐ A check is attached in the amount required under 37 CFR § 1.17(p).

RELATED CASES

☐ Attached is a list of applicant's pending applications or issued patents which may be related to the present application. A copy of the patent(s) is attached along with PTO/ SB/08.

☐ A check is attached in the amount required under 37 CFR § 1.17(p).

CERTIFICATION

The undersigned certifies that

☐ each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

☐ no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.

PETITION

☐ Applicant(s) hereby request consideration of the attached information. A check is attached in the amount of the Petition fee required under 37 CFR § 1.17(i)(1).

DEPOSIT ACCOUNT

■ Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit account No. 50-0911. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
MCKENNA LONG & ALDRIDGE LLP

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Date: January 24, 2006

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	[redacted]549,804
Filing Date	[redacted]ptember 19, 2005
First Named Inventor	WALLEY, Keith R.
Art Unit	TBA
Examiner Name	TBA
Attorney Docket Number	28903.0003 (SBF-3)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US 5,128,247			
	A2	US 5,130,423			
	A3	US 5,674,743			
	A4	US 5,945,515			
	A5	US 5,989,431			
	A6	US 6,025,136			
	A7	US 6,270,961			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]	Number[4]	Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	B1	WO	01/81631					
	B2	WO	98/53098					

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Cited[1]	T[2]
	C1	American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis (Critical Care Medicine (1992) 20(6):864-874.	
	C2	Analects, (1994) Vol. 22, No. 4 Pharmacia Biotech.	
	C3	Anonymous, Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. New England Journal of Medicine (2000) 342(18):1301-8.	
	C4	Anvari, A., et al. PAI-1 4G/5G polymorphism and sudden cardiac death in patients with coronary artery disease. Thrombosis Research (2001) 103(2):103-7.	
	C5	Axelrod, V.D., et al. Specific terminal of RNA polymerase synthesis as a method of RNA and DNA sequencing. NuclAcids Res (1978) 5(a): 3549-3563	

Examiner Signature		Date Considered	

DC:50377013.1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 **Applicant's** unique citation designation number **(optional)**. 2 See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 3

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS (...cont.)

Examiner Initials *	Cite No.[1]	Document Cited	T
	C6	Benza, Raymond L. "Association of a gene polymorphism for PAI-1 with primary pulmonary hypertension" American Heart Association Cardiopulmonary and Critical Care Council Newsletter, 23(1), Spring 2002, p. 7-8.	
	C7	Bernard, G.R., et al. The effects of ibuprofen on the physiology and survival of patients with sepsis. New England Journal of Medicine (1997) 336(13):912-8.	
	C8	Bernard, G.R., et al. Efficacy and safety of recombinant human activated protein c for severe sepsis. New England Journal of Medicine (2001) 344(10):699-709.	
	C9	Binder, B.R., et al. Plasminogen activator inhibitor 1: physiological and pathophysiological roles. News in Physiological Sciences (2002) 17:56-61.	
	C10	Boekholdt, S.M., et al. Genetic variation in coagulation and fibrinolytic proteins and their relation with acute myocardial infarction. Circulation (2001) 104(25):3063-8.	
	C11	Catchpoole, DR, Lock, RB. "The potential tumour suppressor role for caspase-9 (CASP9) in the childhood malignancy, neuroblastoma", Eur J Cancer (2001) 37(17):2217-21.	
	C12	Dawson, S.J., et al. The two allele sequences of a common polymorphism in the promoter of the plasminogen activator inhibitor-1 (PAI-1) gene respond differently to interleukin-1 in HepG2 cells. Journal of Biological Chemistry (1993) 268(15):10739-45.	
	C13	Dawson, S., et al. Genetic variation at the plasminogen activator inhibitor-1 locus is associated with altered levels of plasma plasminogen activator inhibitor-1 activity. Arteriosclerosis & Thrombosis (1991) 11(1):183-90.	
	C14	Endler, G., et al. The 4G/5G genotype at nucleotide position -675 in the promotor region of the plasminogen activator inhibitor 1 (PAI-1) gene is less frequent in young patients with minor strike than in controls. British Journal of Haematology (2000) 110(2):469-71.	
	C15	Eriksson, P., et al. Allele-specific increase in basal transcription of the plasminogen-activator inhibitor 1 gene is associated with myocardial infarction. PNAS (1995) 92(6):1851-5.	
	C16	Fourrier, F., et al. Septic shock, multiple organ failure, and disseminated intravascular coagulation: compared patterns of antithrombin III, protein c, and protein s deficiencies. Chest (1992) 101(3):816-23.	
	C17	Freeman, B.D., et al. Template-directed dye-terminator incorporation with fluorescence polarization detection for analysis of single nucleotide polymorphisms implicated in sepsis. J Mol Diagnostics (2002) 4(4):209-215.	
	C18	Gaillard, MC, Mahadeva, R., Lomas DA. "Identification of DNA polymorphisms associated with the V type alpha1-antitrypsis gene", Biochim Biophys Acta (1999) 1444(20:166-70.	
	C19	Gardemann, A., et al. The 4G4G genotype of the plasminogen activator inhibitor 4G/5G gene polymorphism is associated with coronary atherosclerosis in patients at high risk for this disease. Thrombosis & Haemostatis (1999) 82(3):1121-6.	
	C20	Haralambous, E., et al. Role of functional plasminogen-activator-inhibitor-1 4G/5G promoter polymorphism in susceptibility, severity, and outcome of meningococcal disease in caucasian children. Crit Care Med (2003) 31(12):2788-93.	
	C21	Hermans, P.W., et al. 4G/5G promoter polymorphism in the plasminogen-activator-inhibitor-1 gene and outcome of meningococcal disease. Lancet (1999) 354(9178):556-60.	
	C22	Hesselvik, J.F., et al. Coagulation, fibrinolysis, and kallikrein systems in sepsis: relation to outcome. Critical Care Medicine (1989) 17(8):724-33.	
	C23	Hindorff, L.A., et al. The association of PAI-1 promoter RG/5G insertion/deletion polymorphism with myocardial infarction and stroke in young women. Journal of Cardiovascular Risk (2002) 9(2):131-7.	
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	C25	Johnson, K., et al. Potential mechanisms for a proinflammatory vascular cytokine response to coagulation activation. Journal of Immunology (1998) 160(10):5130-5.	
	C26	Johnson, K., e t al. The proinflammatory cytokine response to coagulation and endotoxin in whole blood. Blood (1996) 87(12):5051-60.	

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS (...cont.)

Examiner Initials *	Cite No.[1]	Document Cited	T
	C27	Jones, K., et al. The influence of 4G/5G polymorphism in the plasminogen activator inhibor-1 gene promoter on the incidence, growth and operative risk of abdominal aortic aneurysm. European Journal of Vascular & Endovascular Surgery (2002) 23(5):421-5.	
	C28	Lopez-Aguirre, Y., et al. Endothelial cell and hemostatic activation in relation to cytokines in patients with sepsis. Thrombosis Research (1999) 94(2):95-101.	
	C29	Lorente, J.A., et al. Time course of hemostatic abnormalities in sepsis and its relation to outcome. Chest (1993) 103(5):1536-42.	
	C30	Menges, T., et al. Plasminogen-activator-inhibitor-1 4G/5G promoter polymorphism and prognosis of severely injured patients. Lancet (2001) 357(9262):1096-7.	
	C31	Mesters, R.M, et al. Factor VIIa and antithrombin III activity during severe sepsis and septic shock in neutropenic patients. Blood (1996) 88(3):881-6.	
	C32	Mesters, R.M, et al. Increase of plasminogen activator inhibitor levels predicts outcome of leukocytopenic patients with sepsis. Thrombosis & Haemostatis (1996) 75(6):902-7.	
	C33	Mikkelsson, J., et al. Plasminogen activator inhibitor-1 (PAI-1) 4G/5G polymorphism coronary thrombosis, and myocardial infarction in middle-aged Finnish men who died suddenly. Thrombosis & Haemostatis (2000) 84(1):78-82.	
	C34	Noguchi, E., et al. "Identification of missense mutation in the IL12B gene: lack of association between IL12B polymorphisms and asthma and allergic rhinitis in the Japanese population", Genes Immun (2001) 2(7):401-3.	
	C35	Ortlepp, J.R., et al. The 4G/5G promotor polymorphism of the plasminogen activator inhibitor-1 gene and late lumen loss after coronary stent placement in smoking and nonsmoking patients. Clinical Cardiology (2001) 24(9):585-91.	
	C36	Phillipe, J., et al. Fibrinolysis and coagulation in patients with infectious disease and sepsis. Thromb Haemost (1991) 65(3):291-5.	
	C37	Pralong, G., et al. Plasminogen activator inhibitor 1: a new prognostic marker in septic shock. Thromb Haemost(1989) 61(3):459-62.	
	C38	Rieder, M.J., et al. Accession AF386492 Vol. 2001: Seattle SNPs. NHLBI Program for Genomic Applications, UW-FHCRC, Seattle, WA (2001).	
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	C40	Russell, J.A. Genetics of Coagulation factors in acute lung injury. Critical Care Medicine (2003) 31(4)S243-S24.	
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	C42	Segui, R., et al. PAI-1 promoter 4G/5G genotype as an additional risk factor for venous thrombosis in subjects with genetic thrombophilic defects. British Journal of Haematology (2000) 111(1):122-8.	
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	C44	Tabrizi, A.R., et al. Genetic markers in sepsis. J Am Coll Surg (2001) 192(1):106-117.	
	C45	Vincent, et al. Scoring systems for assessing organ dysfunction and survival. Critical Care Clinics (2000) 16:353-366.	
	C46	Westendorp, R.G, et al. Variation in plasminogen-activator-inhibitor-1 gene and risk of meningococcal septic shock. Lancet (1999) 354(9178):561-3.	

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